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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED
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GROUP 1600

Application Number: 09/813,292
Filing Date: March 21, 2001
Appellant(s): KRINGELUM ET AL.

Stephen A. Bent
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 6, 2007 appealing from the Office action mailed July 7, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Regarding claim 28, appellant has requested clarification as to the disposition of the claim. Specifically in that claim 28 is indicated as rejected on the Office Action Summary, however was not included in the heading of the rejections.

For clarification, claim 28 was intended to be recited in the heading of the first cited rejection, namely Sing in view of Kosikowski and Christensen (claims 1 – 7, 11, 17 – 22, 24 – 31). The limitations of claim 28 further define claim 1 in that a plurality of subsets are provided for different propagation factories or plants, rather than a single subset be provided to a single factory or plant. Moreover, the claim is drawn to subsets, factories and plants in the plural form, not a single subset, factory or plant. These limitations were clearly considered and addressed, as the body of the rejection identifies with multiple subsets, factories and plants. Specifically, in summarizing the claims of appellant, the rejection clearly identifies "providing subsets to different factories/plants", "inoculating the mediums at different locations", and "repeated with another subset of the stock at different factories/plants", each of which are in the plural form (pages 3 – 4 of the Final Rejection). In addition, when discussing the teachings of the prior art, the rejection clearly identifies with multiple subsets, factories and plants as evidenced by pages 5 – 6 wherein the rejection refers to "multiple growth mediums" (or multiple subsets) and "wherein the subsets are provided to different factories and/or plants". Thus, exclusion of claim 28 from the rejection heading was clearly a typographical error by the examiner.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6146667	SING et al.	11-2000
5098721	KOSIKOWSKI et al.	03-1992
3483087	CHRISTENSEN	12-1969
4476143	CZULAK et al.	10-1984
5952020	LIZAK	09-1999
6068774	VANDENBERGH et al.	05-2000
5225346	MATSUMIYA et al.	07-1993
3980523	RIMLER et al.	09-1976

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 – 7, 11, 17 – 22, 24 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski and Christensen.

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid

fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a

matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Claims 1 – 7, 11, 17 – 22, 24 – 27and 29 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Christensen and Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c) inoculating the mediums at different factories/plants with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the

medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are

named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Claims 1 – 11, 17 – 22, 24 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Christensen and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c) inoculating the mediums at different factories/plants with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium,

Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets are combined with an aqueous medium to obtain a suspension before cultivating. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one

of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of

stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Claims 1 – 7, 11 – 22, 24 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Vanderbergh and Matsummiya.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium,

Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are

named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

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Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenbergh teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such containers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Maysumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective

variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

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0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are

named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein each of the named organisms are used. However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of inoculating milk with Lactobacillus and Streptococcus cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been

motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

Claims 1 – 7, 11, 17 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Koskowski, Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of

subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products such as enzymes, active substances, polysaccharides or amino acids; or produce desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, and plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps of inoculation take place

does not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the step of inoculating mediums with subsets of stock inoculum. Absent evidence that practicing the method step of inoculating a medium in different propagation factories and/or plants would materially change the method step from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of Haemophilus in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically

altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

(10) Response to Argument

Appellant argues that no prima facie case has been made in that the references do not teach the methods wherein subsets are provided to different propagation factories and/or plants, but that Sing teaches multiple propagation steps in multiple growth media; that starter cultures with consistent qualities are not disclosed; and that all limitations have not been considered. Appellant further argues the references do not teach the quality tests of claim 29, but tests that are related to producing a quality cheese, not a quality culture; that the tests disclosed are different from those recited in claim 29; and that the context of the tests are different, thus one would not be motivated to combine the tests of the prior art with the methods of Sing. Finally, appellant states that Christensen is cited in the last three rejections, however is not cited in the heading of the rejection.

However, these arguments fail to persuade because of the following reasons. All of the claimed limitations have been fully addressed by the combination of the cited references as stated in the rejections above. Specifically, the rejections clearly state that while the references do not teach the subsets are provided to different factories and/or plants, the location of where the actual step of inoculation occurs does not patentably distinguish the method from those of the prior art. It is pointed out that the methods obtained by the combined teachings of the cited references suggests to one in the art that a stock inoculum can be divided into subsets as a matter

of routine practice. Kosikowski clearly teaches common practices wherein mother cultures (starter cultures) are transferred (or inoculated) into multiple growth media. Each growth medium could reasonably be interpreted as its own propagation factory of the starter culture as each medium is in a separate location. Further, since the references teach that the starter cultures are used to inoculate multiple media, one in the art would have been motivated to inoculate different media with a reasonable expectation for successfully supplying a starter culture of consistent quality. Whether the inoculation occurs on the same media, different media, different rooms, different locations or even different factories and/or plants, the step of inoculating a starter culture into multiple, separate and different media is still practiced. Thus, the step of inoculating multiple growth media from a single starter culture is suggested and practiced by the prior art. Moreover, the location of where the actual step of inoculation occurs does not patentably distinguish the method steps absent evidence to the contrary.

Regarding the teachings of Sing, it is noted that the rejections are supported by a combination of references, not the single disclosure of Sing. Thus, the combination of cited reference suggests both single and multiple inoculations of a starter culture into one and multiple media. In addition, it is noted that the claims are not limited to a particular number of propagation or inoculation steps, but encompass multiple inoculations in multiple growth media.

Regarding appellant's argument that a consistent quality is not disclosed, the method obtained by the combination of cited references clearly identify and suggest to one in the art that a single starter culture can be used to inoculate multiple growth media. Thus, one in the art would expect a consistent quality between the various media that are inoculated by the starter

culture. In addition, Christensen further supports the practice of obtaining cultures with consistent quality by using a starter culture.

Regarding claim 29, it is noted that the claim includes a count of total viable cells, determination of metabolic activity and/or fermentation tests. Christensen clearly teaches plate counts (count of total viable cells) in addition to activity tests (which may include metabolic activity and fermentation tests as claimed) (col.6). Thus, the specific tests were clearly known in the art and practiced as quality control measures with starter cultures. While the reference suggests that by practicing these quality tests on the starter cultures, a higher quality of food product can be obtained, the reference still clearly teaches the tests ensure quality of the starter culture itself (col.6).

Finally, regarding Christensen, it is noted that the reference is relied upon to evidence that testing and storing cultures was a known practice in the art at the time the claimed invention was made. Thus, the reference evidences that it was well known to practice those steps as a matter of routine experimentation. While the rejections do not recite the reference in the heading, it is relied upon to support the assertions of "state of the art" made by the examiner.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ruth A. Davis/

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